REMARKS/ARGUMENTS

Claims 1-25 are pending.

Interview of 21 April 2003

Applicants acknowledge the Examiner's time and courtesy during the personal interview of 21 April 2003. As acknowledged on the Interview Summary, the Examiner indicated that the Applicants did not need to provide a separate interview summary. But after receiving and reviewing the February 2003 revisions to the M.P.E.P., Applicants are hereby providing a summary of the interview pursuant to §713.04.

Brief Description of any Exhibit or Demonstration

None.

Identification of the Claims Discussed

Claims 1, 10, and 21-25 were discussed.

Identification of Specific Prior Art Discussed

U.S. Pat. Nos. 5,536,526 (Virtanen) and 5,204,115 (Olinger).

Identification of Principal Proposed Amendments

Amendments to claims 10, and 23-24 were discussed. Other proposed amendments are discussed in the Interview Summary.

General Thrust of Principal Arguments

Amendments were discussed with respect to claims 23 and 24 to remove the rejections under 35 U.S.C. §112. Also, Applicants pointed out that a solution would inherently be substantially homogeneous (relevant to currently amended claim 24 and claim 25). The amendments to claims 23 and 24 are depicted in the claims and will be discussed further below in response to the office action.

With respect to product claims 1 and 21, Applicants respectfully asserted that the declaration submitted with the preliminary amendment of July 1, 2002, provided sufficient evidence that the features of dissolving xylitol in these claims created a distinct product from those products disclosed in Virtanen or Olinger. Consequently, Applicants respectfully

submitted that the product claims are patentable.

With respect to process claims 10 and 22, neither Virtanen or Olinger teaches or suggests producing an aqueous solution by dissolving xylitol (relevant to claim 10) and making an aqueous solution of xylitol and at least one other polyol (relevant to claim 22). Consequently, the rejections in view of these references should be withdrawn.

Office Action of 23 December 2002

Claim Rejections Under 35 U.S.C. §112, first paragraph

Claims 24-25 stand rejected as allegedly not containing subject matter not described in the specification. Particularly, the Action alleges that "substantially homogenous distribution" and "solution is substantially homogenous" are not supported in the claims.

As discussed above, a solution is inherently substantially homogenous. Consequently, support is provided for claim 25. Similarly, claim 24 has been amended to state that the tabletting aid has a substantially homogenous solution distribution. Thus, Applicants respectfully submit that these rejections should be withdrawn.

Claim Rejections Under 35 U.S.C. §112, second paragraph

Claims 23-24 stand rejected as allegedly being indefinite. Applicants have amended claim 23 to recite an --or-- after paragraph b1) in claim 23 and to replace "at least one particle of the" with --the tabletting-- aid to provide antecedent basis and clarify the term "aid". Applicants respectfully submit that these amendments do not narrow the scope of the claims.

Claim Rejections Under 35 USC §102(b)

Claims 1, 2, 4, 5-7, 9, 12, 13, 19-21 and 24 stand rejected as allegedly anticipated by U.S. Pat. No. 5,536,526 (Virtanen) and claims 1, 2, 4, 5, 9, 12-16, 18, and 21-25 stand rejected as allegedly anticipated by U.S. Pat. No. 5,204,115 (Olinger). Applicants respectfully traverse these rejections.

With respect to the process claims (relevant to claim 22), Applicants respectfully submit that neither Virtanen or Olinger teaches or suggests producing an aqueous solution by dissolving xylitol (relevant to claim 10) and making an aqueous solution of xylitol and at least one other polyol (relevant to claim 22). Particularly, Virtanen discloses granulating xylitol with a small amount of sorbitol syrup (column 7, lines 20-25) and exemplifies introducing into a granulator 800 kg/hr of powder and 50 l/hour syrup solution (Example 2 at

column 8, lines 40-46). Olinger exemplifies spraying 528.6 grams of polydextrose syrup on 6000 grams of xylitol. See Example 2 at column 9. Consequently, the rejections in view of these references should be withdrawn.

With respect to the product claims (relevant to claims 1 and 21), Applicants respectfully submit that there is no anticipation because both the Virtanen and Olinger patents relate to granulating xylitol, not dissolving the xylitol in a solvent.

In the Examiner's Answer, the Office asserted that the rejected claims are product-by-process claims, and patentability is based on the product and not its method of production.

However, even if the prior art and rationale provided by the Examiner appears to show that the claimed product is allegedly the same or similar to that of the prior art, although produced by a different process, then only the burden shifts to applicant to come forward with evidence establishing an unobvious (or novel) difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) and M.P.E.P. §2113.

A declaration previously submitted with the preliminary amendment of July 1, 2002, provides evidence where the declarant attests to the differences between spraying a sorbitol solution onto a xylitol bed (relevant to Virtanen and Olinger) and co-spraying a xylitol-sorbitol solution onto a xylitol-sorbitol bed (relevant to the present invention). These experiments were carried out as described by Example 2 of Virtanen in order to prepare powders containing 97% of xylitol and 3% sorbitol. Moreover, the experiments were carried out using a SHUGI granulator.

As depicted in the scanning electron microscopy pictures, powders TG27/1 and TG28/1 (relevant to Virtanen and Olinger) depict particles with a needle structure. In marked contrast, powder TG31/1 (relevant to the present invention) does not show this needle structure. Rather, the surface of powder TG31/1 is composed of a mixture of sorbitol and xylitol. Consequently, the spraying techniques relevant to Virtanen and Olinger result in different structural properties of powder particles as compared to spraying techniques of the present invention. Also, the experiments demonstrate that introducing sorbitol solution and xylitol to a granulator does not form a homogeneous solution prior to granulation. Therefore, Applicants respectfully submit that this declaration provides more than sufficient evidence to establish the unobvious and novel differences between the claimed product and the prior art product.

Moreover, the cited references in the Action support the contention that the granulates of Virtanen and Olinger are inhomogeneous. Particularly, Virtanen discloses:

> The granulation process is fundamentally different from the dry mixing of two polyols such as xylitol and sorbitol, such as that disclosed by G. B. Patent Nos. 1,526,020. **The granulation process results in the crystallization of some of the sorbitol or present onto the surface of the xylitol particles forming fine, needle like protrusions.** These needle like protrusions can be seen by electron microscopes, and a photograph showing the granulate of the present invention (with xylitol present in an amount of about 97% by weight, and sorbitol present in an amount of about 3% by weight) is shown in FIG. 1; the needle like crystals can be clearly seen. It is thought that the needle like protrusions are, or at least contribute to, the compressibility of the granulate of the present invention. Blends of xylitol and sorbitol in the proportion covered by the present invention which are simply admixed do not exhibit adequate compressibility and do not exhibit the needle like protrusions in electron micrographs such as those seen in FIG. 1.

Column 7, line 61, - column 8, line 11, emphasis added.

Thus, granulating forms sorbitol needle like protrusions on xylitol particles (an inhomogeneous composition) versus dissolving the xylitol in a solvent, which creates a homogenous composition. Thus, Applicants respectfully submit that there is more than sufficient evidence in the record to demonstrate the patentability (both novelty and unobviousness) of Applicants' invention, and these prior art rejections should be withdrawn.

What is more, Virtanen fails to teach a tabletting aid produced by dissolving the xylitol in a solvent. Rather, Virtanen granulates xylitol crystals. As discussed in Virtanen, the granulation process involves agglomerating crystalline xylitol (ground or otherwise comminuted to a small particle size) by means of polyol based syrup (column 6, lines 25-29). Thus, a granulation process involves the mixing of two or more ingredients in a solid state and leads to inhomogeneous granules. In marked contrast, the tabletting aid of the present invention is produced by dissolving the xylitol in a solvent forming a homogeneous solution. Evaporating the solvent by spray drying or fluidized bed granulation leads to a homogenous tabletting aid.

Olinger discloses a directly compressible, non-cariogenic xylitol granulate which comprises xylitol and a binder in the range of about 0.1% to about 5% by weight, wherein the binder is physiologically acceptable, non-cariogenic and is taken from the group consisting of polymerized reducing sugars, alkali carboxymethylcellulose and hydrogenated starch hydrolysate (column 5, line 65 to column 6, line 4). In one method, an aqueous binder

solution is added to milled xylitol, and the resulting granulate is dried and screened. (Column 7, lines 8-10). Thus, Olinger adds a solution to the granulate, but does not dissolve the granulate. Olinger also discloses a directly compressible granulate comprising a polyol such as mannitol, lactitol, sorbitol, isomalt and maltitol or a sweetener suitable for diabetic applications such as crystalline fructose and/or mixtures thereof, and a polydextrose binder present in the range of about 0.1% to about 5% by weight. (Column 7, lines 16-22).

As discussed above for Virtanen, granulating is not the same as dissolving the xylitol in a solvent and spray drying or fluidized bed granulation. Olinger fails to teach a tabletting aid produced by dissolving the xylitol in a solvent. Thus, there is no anticipation of the claimed invention.

Claim Rejections Under 35 USC §103

Claims 1-16 and 18-25 stand rejected as allegedly obvious by Virtanen in view of U.S. Patent No. 5,958,471 (Schwarz). Applicants respectfully traverse these rejections.

Virtanen, as discussed above, granulates xylitol crystals. Schwarz relates, at least in part, to compositions obtainable by dissolving at least two polyols in water (column 2, lines 7-8). Virtanen fails to teach the desirability of dissolving the xylitol crystals in a solvent for, after subsequent processing, creating a tabletting aid. The mere fact that references can be combined or modified does not render the resultant combination *prima facie* obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990), M.P.E.P. §2143.01. Here, Virtanen's requirement that crystals of xylitol contain a surface coating of crystals of another polyol teaches against forming a homogenous solution of xylitol and polyol prior to crystallizing. Thus, there is no motivation to combine these references. Further demonstrating the lack of motivation to combine these references, Schwarz broadly defines the suitable range of "between 50:50 and 99:1" for compositions of sorbitol and xylitol at col. 2, lines 13-15. This ratio is inconsistent with the proportions required by Virtanen, namely 94% -98% xylitol (column 5, lines 38-43). There is no teaching or suggestion to modify the composition proportions of Schwarz to make them compatible with Virtanen. Lacking this teaching, there is no motivation to support this combination of references.

Claims 1, 2, 4, 5, 9, 12-18, and 21-25 stand rejected as allegedly obvious by Virtanen in view of U.S. Patent No. 5,576,014 (Mizumoto).

Mizumoto fails to cure the deficiencies in the Virtanen reference because Mizumoto's dissolving compressed molding is also made by mixing or granulating various components, *see e.g* column 7, lines 19-46. Consequently, there is no *prima facie* case of obviousness.

Supererogatorily, the present invention exhibits significant and unexpected results. A *prima facie* case of obviousness based on similarity is rebuttable by proof that the claimed invention possesses unexpectedly advantageous or superior properties. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and M.P.E.P. §2144.09.

The Action of September 12, 2000, and the Examiner's Answer allege that there is no criticality in the amount of a particular component, *e.g.* xylitol, because the prior art obtains the same results desired by Appellant, *i.e.* a direct compressed tablet. This Action also alleges that the amount has not been shown to provide any unusual and/or unexpected results over the applied prior art.

Appellant traverses these allegations. As discussed in the present specification, comparative example 2, pure xylitol, even spray dried, does not possess the required tabletting properties. Rather, the addition of up to 10%, preferably 5-10%, of a second polyol, preferably mannitol, can achieve the desired results (see, e.g. Examples 1-4). Consequently, Applicants respectfully submit that the present invention exhibits significant and unexpected results, at least due, in part, to the disclosure in the present specification.

In view of the above, favorable reconsideration is courteously requested. If there are any remaining issues which can be expedited by a telephone conference, the Examiner is courteously invited to telephone the undersigned at the number indicated below.

Respectfully submitted,

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